

Practitioner's Docket No. MPI1999-037P1RCP1M**REMARKS**

Claims 23-32 were rejected under 35 USC 101 for lack of a specific and substantial asserted utility or a well established utility. The rejection is traversed.

Applicant's again submit respectfully that in fact a *specific* and *substantial* utility is *asserted* in the present application for use of the claimed nucleic acids. Applicants have asserted at least that the presently claimed compositions are useful in the identification of compounds which modulate LGR6 in an attempt to identify candidate compounds for treatment of LGR6 related disorders, including for example, metabolic disorders.

Applicants respectfully submit the Examiner has not met the requirement to establish a *prima facie* showing that one of skill in the art would not consider credible the asserted specific and substantial utility asserted in the present application (e.g., use for identification of diagnostics and/or therapeutics in metabolic disorders, eg, weight disorders). In order to make such a showing, the Examiner must provide a clear explanation refuting such utility as well as factual findings to support such conclusions.

According to the Utility Guidelines issued, a specific utility is met, for example, when a method for identifying compounds which modulate a receptor is asserted. See Utility Guidelines Training Materials, Example 12. Further, a substantial utility is met, for example, when a specific disclosed disease or condition for treatment using the identified compound is asserted. See Utility Guidelines Training Materials, Example 12. Here, in contrast to the referenced example, specific disorder is in fact identified. Applicants have set forth use of identified compounds in, metabolic (e.g., weight disorders), cardiovascular, or CNS disorders. The identified utility is specific, and the use is based on Applicants identification of regulated expression. See, e.g., page 27, lines 8-10, lines 22-30, page 86, line 5 through page 93 line 8. For example, LGR6 expression is regulated in developing mouse and demonstrates expression in fat and hypothalamic tissues (tissues known to be involved in regulation of metabolic disorders). Thus, as asserted, the identified compounds may be useful in therapies for weight disorders. See page 27 line 31 through page 28 line 6 and Example 2. This is in stark contrast to the Training Materials, Example 12, where no such use is asserted.

In addition, Applicants respectfully would like to point out the Examiner that utility for research tools, such as, for example receptors for screening for candidate therapeutic compounds, is a recognized utility. In fact, the Office recognizes that intermediate, or research tool utilities can and do satisfy the Utility requirement. For example MPEP 2107.01 section addressing research tools:

Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds).

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Applicants respectfully submit the specific substantial utility asserted is a credible utility. Further, Applicants submit the Examiner has not met the requirement for an effective rebuttal of the asserted utility under the Utility Guidelines Training Materials. Under the Guidelines:

An assertion is credible unless

(A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use.

See Utility Guidelines Training Materials page 3.

Where a specific and substantial utility is set forth, the Examiner must provide a prima facie showing of lack of credibility. According to the Utility Guidelines as set forth in the MPEP:

Where the asserted specific and substantial utility is not credible, a prima facie showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. The prima facie showing must contain the following elements:

(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

See MPEP 2107.

In contrast to the outlined requisite showing, the Examiner here merely refuses to accept the asserted utility and cites generic policy statements and again re-asserts that the disclosure refers only generally to any LGR6 related disorders, that the sole reason for utility is based in homology to HG38, and no significance has been attributed to LGR6. There is no clear explanation for why the reasoning for the asserted utility is flawed, rather the Examiner merely dismisses any arguments Applicants' have outlined related to the specific asserted utility set forth in the specification. In view of the foregoing, Applicants respectfully submit the rejection under 35 USC 101 is undue and improper. Thus, withdrawal of the rejection is requested.

Claims 23-32 were also rejected under 35 USC 112, first paragraph because the claimed invention purportedly lacks utility. For the reasons stated herein rejection is traversed. Withdrawal of the rejection is requested.

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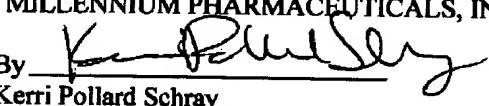
Claim 23 was rejected under 35 USC 112, first paragraph for lack of written description, because of unclear metes and bounds of the limitation of "LGR6 activity." The rejection is traversed.

Applicants have amended claim 23 so as to eliminate "LGR6 activity" It is believed the amendments contained herein renders the rejection moot. Withdrawal of the rejections is thus requested.

This paper is being filed timely and it is believed no extensions of time or fees are required. In the event any extensions of time or fees are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

<u>29 July 2003</u>	MILLENNIUM PHARMACEUTICALS, INC. By  Kerri Pollard Schray Registration No. 47,066 75 Sidney Street Cambridge, MA 02139 Telephone - 617-551-3676 Facsimile - 617-551-8820
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